

## Senate Bill No. 293

### CHAPTER 827

An act to add Article 7.5 (commencing with Section 4127) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacies, and making an appropriation therefor.

[Approved by Governor October 12, 2001. Filed  
with Secretary of State October 13, 2001.]

I am signing Senate Bill 293 which would require the Board of Pharmacy (BOP) to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy, require some pharmacies that compound these drug products to be specially licensed and provide for inspection and investigations of compounding pharmacies. The bill appropriates \$580,000 from the Pharmacy Contingent Fund for this purpose.

The Board advises that due to the length of time necessary to promulgate regulations, this bill will not be implemented until the next budget year. As a consequence, I am deleting the funds and will review any funding and related positions as part of next year's budget process.

GRAY DAVIS, Governor

#### LEGISLATIVE COUNSEL'S DIGEST

SB 293, Torlakson. Pharmacies: injectable sterile drug products.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. Existing law regulates controlled substances, dangerous drugs, and dangerous devices.

This bill would authorize the California State Board of Pharmacy, based on reasonable belief obtained during an investigation or pharmacy inspection, to issue a cease and desist order to a pharmacy requiring the pharmacy to refrain from compounding injectable sterile drug products if that activity poses an immediate threat to the public health or safety. The bill would implement quality assurance methods regarding the compounding of injectable sterile drug products. The bill would require the board to adopt necessary regulations regarding injectable sterile drug products. The bill would require specified pharmacies to obtain a license from the board in order to prepare injectable sterile drug products. The bill would provide that the reconstitution of a sterile powder would not require a license if specified conditions are met. By charging a fee for these licenses which would be deposited into the continuously appropriated Pharmacy Board Contingent Fund, the bill would make an appropriation.

This bill would provide that a violation of the bill or regulations adopted pursuant to it would be subject to a fine of up to \$2,500. These



finances would be deposited into the continuously appropriated Pharmacy Board Contingent Fund and would thereby make an appropriation. This bill would appropriate \$580,000 from the Pharmacy Board Contingent Fund for purposes of the bill.

A violation of the Pharmacy Law is a crime. By adding additional requirements to the Pharmacy Law concerning injectable sterile drug products, this bill would impose a state-mandated local program by creating a new crime.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Appropriation: yes.

*The people of the State of California do enact as follows:*

SECTION 1. It is the intent of the Legislature in enacting this act to increase the regulatory scrutiny of the compounding of sterile injectable drug products in pharmacies in order to improve public safety. The compounding of injectable sterile drug products in pharmacies benefits patients throughout California and is an essential health care service.

Effective July 1, 2002, the sum of five hundred eighty thousand dollars (\$580,000) is hereby appropriated from the Pharmacy Board Contingent Fund to the California State Board of Pharmacy for the costs associated with the implementation of this act, including, but not limited to, the salaries and benefits of the employees required to implement this act.

SEC. 2. Article 7.5 (commencing with Section 4127) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.5. Injectable Sterile Drug Products

4127. The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

4127.1. (a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued



to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Health Services and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:

(1) The sterile powder was obtained from a manufacturer.

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(f) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

4127.2. (a) A nonresident pharmacy may not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products may not be issued or renewed until the board receives the following from the nonresident pharmacy:

(1) A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.

(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of



Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(d) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

4127.3. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding injectable sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding injectable sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.

(c) The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

4127.4. Notwithstanding any other provision of law, a violation of this article, or regulations adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to two thousand five hundred dollars (\$2,500) per occurrence pursuant to a citation issued by the board.

4127.5. The fee for the issuance of a license, or renewal of a license, to compound sterile drug products shall be five hundred dollars (\$500) and may be increased to six hundred dollars (\$600).

4127.6. This article shall become operative upon the allocation of positions to the board for the implementation of the provisions of this article in the annual Budget Act.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

